

Application No. 10/663,568
Amendment dated: August 25, 2008
Reply to Office action of May 23, 2008

REMARKS/ARGUMENT

IDS Issue

In the Information Disclosure Statement filed October 14, 2003, two references, B46 and B47, were not initialed by the Examiner as having been considered. The Examiner has indicated that it was inadvertent and that an initialed copy would be sent with the next communication from the Office, which would have been the present Office Action. No initialed IDS documents were received with the present Office Action. Therefore, Applicants respectfully request a copy with the next communication from the Office.

Description of Amendments

Claims 25, 27-32, and 34-37 are pending.

Claim 32 has been amended. Claims 34-37 have been added. Support for claim 34 is found in the specification at page 6, line 31 to page 7, line 7. Support for claim 35 is found on page 19, lines 3-11. Support for claims 36-37 is found on page 3, lines 27-28 and Figure 2. No new matter has been added.

Applicant respectfully requests reconsideration in view of the foregoing claim amendments and remarks presented below.

First Rejection under 35 U.S.C. §103

Claims 25 and 28-30 have been rejected under 35 USC § 103(a) as obvious over U.S. Patent No. 6,719,998 Golomb et al.

Claim 25 of the present invention has the limitation that “the coating layer comprises a polymer different than the polymer from which the particles are made.” The Examiner has provided no rationale for modifying the teachings of Golomb et al. so that it teaches the above-mentioned claim limitations.

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. Indeed, the Supreme Court states that “Rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. KSR International Co. v. Teleflex Inc. (KSR) (550 U.S. __, 82 USPQ2d 1385, 1396) (KSR). The Examiner, however, has failed to articulate why the teaching of Golomb et al. could have been modified to teach the above claim limitations. The Examiner simply states that the invention, “when taken as a whole”, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

The formulations of Golomb et al. are quite different from those of the present invention. Liposomal preparations are used to encapsulate an active ingredient. These liposomes are then delivered via various methods, including direct injection using a liquid carrier solution. Although Golomb et al. say that a stent may be coated with the “delivery system,” there are no specific methods given. In the only example disclosed, an IV injection delivery is used.

With regard to claim 28, the Examiner is using the wrong standard for showing obviousness. First, the Examiner must establish a *prima facie* case of obviousness. This clearly has not happened in this case. The Examiner states on page 3 of the Final Office action dated May 23, 2008 that “the active ingredient may be formulated in a manner, for example, by including it within a coating of the stent. Examples of coating are polymer coatings, e.g., made of polyurethane or a gel (col. 3, lines 47-60).” Claim 31 of the present invention requires that the polymeric particles have a hydrogel consistency. Golomb et al. teach that the active ingredient may be included within a coating of the stent, where the coating may be a gel. Further, the multiple polymer system of the present invention provides a mechanism for allowing the polymeric particles to have a different consistency from the rest of the coating. Using the one-polymer method disclosed in Golomb et al., it is not even clear how to achieve having only the drug particles in a hydrogel form, as opposed to just having the drug particles mixed in a gel that is the entire coating. Thus, the entire coating in Golomb et al. is a gel, as opposed to the polymeric particles of the present invention having a hydrogel consistency.

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The Examiner merely states on page 8 of the Final Office Action dated May 23, 2008 that there is “no showing of any unexpected results with respect to the polymeric material formed of a hydrogel material. The polymeric particles of the art provide for the same beneficially effective results for sufficiently treating restenosis.” As mentioned above, before the Examiner has established a *prima facie* case of obviousness, there is no burden on the Applicants to show unexpected results.

Because claims 29 and 30 depend from claim 25, they are also not obvious in view of Golomb et al. Reconsideration and withdrawal of the rejections are respectfully requested.

Second Rejection under 35 U.S.C. §103

Claims 27, 31 and 32 have been rejected under 35 USC § 103(a) as obvious over Golomb as applied to claim 25 and 28-30 and further in view of U.S. Patent No. 6,379,379 to Wang.

Claim 32, as amended, requires the therapeutic substance to be completely encased within the polymer particles. As mentioned above, Golomb et al. fail to teach or suggest this limitation. Wang also does not teach this limitation.

As mentioned above in the previous section, Golomb et al. fail to teach or suggest the present invention under § 103(a). Wang fails to remedy the deficiencies of Golomb et al. with respect to claim 25. Accordingly, claim 25 is patentable allowable over the combination of Golomb et al. and Wang. Claims 27 and 31 depend from claim 25, and are therefore not obvious over the combination of the references for at least the same reason. Reconsideration and withdrawal of the rejections are respectfully requested.

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Conclusion

In light of the foregoing claim amendments and remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

Date: <u>August 25, 2008</u>	<u>/RA/</u>
Squire, Sanders & Dempsey L.L.P. One Maritime Plaza Suite 300 San Francisco, CA 94111 Facsimile (415) 393-9887 Telephone (415) 954-0315 rauerbach@ssd.com	Robert P. Auerbach Attorney for Applicants Reg. No. 46,525